

# EXHIBIT 7



### **Declaration of Craig M. Pratt, M.D.**

I am Craig M. Pratt, M.D. and I have reviewed the case of Mrs. Jo Levitt. My report and opinions follow.

I have been asked to address the question of whether Mrs. Levitt suffered a myocardial infarction in 2000 and whether there is any relationship between Mrs. Levitt's acute coronary syndrome and her use of Vioxx®. I have reviewed the available medical records pertaining to Mrs. Jo Levitt. I have also reviewed and analyzed the relevant medical and scientific literature on Vioxx®.

### **Background and Qualifications**

My qualifications as an expert are outlined in my Curriculum Vitae, which is attached to this report. I am currently a staff cardiologist with The Methodist DeBakey Cardiology Associates in affiliation with The Methodist Hospital Physician's Organization, Houston, Texas. I am an American Board of Internal Medicine certified internist and clinical cardiologist. My current responsibilities include: 1) Director of Research for the Methodist DeBakey Heart & Vascular Center; 2) Program Director, Department of Cardiology; 3) Medical Director of the Coronary Intensive Care Unit at The Methodist Hospital; and 4) Medical Director of the Ambulatory Electrocardiogram Monitoring and Exercise Stress Testing Laboratories at The Methodist Hospital, Houston, Texas.

My other responsibilities include direct patient care, supervision of staff physician and housestaff physician directed patient care, planning and conducting clinical cardiology research, and evaluating new cardiac drugs including the design and conduct of multi-center and multi-national trials. Over the last 25 years I have been a consultant for the U.S. Food and Drug Administration (FDA), including 7 years as Chairman of the Cardio-Renal Advisory Committee to the FDA. In these capacities, I have participated in public hearings, judged the risks and benefits of new cardiovascular therapies and made recommendations to the FDA regarding the approval of new cardiovascular drugs, as well as various issues relating to cardiac toxicity of non-cardiac drugs. I have been an investigator in numerous clinical trials, and a member of numerous institutional review boards and data safety monitoring boards.

I am currently Professor of Medicine at Weill Cornell Medical College (Methodist affiliate) and was previously Professor of Medicine at Baylor College of Medicine. My academic career spans more than 35 years. My academic responsibilities include directorship of the cardiovascular training program and training housestaff including cardiology fellows, internal medicine residents, family practice residents, transitional residents, medical students and other learners at The Methodist Hospital.

I have been the Medical Director of The Methodist Hospital Coronary Intensive Care Unit for over 30 years where I supervise the care of various heart related conditions, including sudden cardiac death, hundreds of myocardial infarctions, and 500-1000 patients annually with acute coronary syndrome.

In formulating my opinion, I rely on my 35 years of experience as a cardiologist, with both an office consultation practice as well as extensive hospital experience in the management of cardiovascular disease. I also rely on the relevant medical and scientific

accelerate atherosclerosis. The Cox-2 studied was MF-tricyclic. This study stands alone and is contrasted by eight other mouse model studies (Burleigh 2002 & 2005; Paul 2000; Pratico 2001; Linton 2002; Oleson 2002; Bea 2003; Egan 2005; and Belton 2003), which have used the same mouse models and concluded Cox-2 inhibitors either had no effect on atherogenesis or were associated with a reduction in atherosclerotic lesion size. Three of these studies specifically tested Vioxx® (Burleigh 2002 & 2005 and Linton 2002) all of which demonstrated a regression of atherosclerosis.

#### **Expert Opinion – Jo Levitt**

Based on my review of the records and materials provided and the relevant medical literature, I offer the following opinions: It is my opinion that (1) Mrs. Levitt did not suffer a myocardial infarction in 2000 (or at any other time based on all available objective criteria); (2) there is no relationship between the acute coronary syndrome that Mrs. Levitt did experience and her treatment with Vioxx; and (3) the body of scientific evidence does not support a conclusion that Vioxx causes acute coronary syndrome.

First, Mrs. Levitt was never diagnosed with a myocardial infarction, nor does my review of her medical records suggest that she had such an event. Mrs. Levitt was hospitalized in March 2000 and treated for acute coronary syndrome. As detailed above, there was no evidence of myocardial infarction during the March 2000 hospitalization or subsequent cardiac testing. She was hospitalized again in May 2000 for in-stent restenosis, and myocardial infarction was again ruled out. Mrs. Levitt suffered no demonstrable damage to her heart function as indicated by her normal left ventricular function throughout her hospitalizations and subsequent cardiac testing. Her significant coronary artery disease noted on catheterization was not surprising given her strong family coronary artery disease history, high cholesterol, and extensive past smoking history. Mrs. Levitt's coronary history and events are fully explained by her established risk factors for the development of atherosclerosis and the natural progression of the disease process.

Second, in contrast to this history of established risk factors for coronary disease, Mrs. Levitt's Vioxx usage cannot plausibly be related to her acute coronary events. Mrs. Levitt took Vioxx for less than seven months before her acute coronary syndrome event on 3/9/00, she took aspirin at the same time she used Vioxx (an irreversible inhibitor of platelet aggregation), and she continued using Vioxx for arthralgias for another two years after her episode of acute coronary syndrome, during which time no additional coronary events occurred.

Finally, there is no scientific evidence supporting a causal relationship between Vioxx and acute coronary syndrome. No significant association was documented by published controlled clinical trials or the final pooled analysis of numerous clinical studies (March 2004). In summary, Mrs. Levitt's clinical circumstances and her cardiac diagnostic procedures, and my understanding of the medical literature do not justify attributing any relationship of Vioxx to her clinical status.

My opinions are based upon the medical records I have reviewed, my clinical experience and my understanding of relevant medical literature. These opinions are expressed to a